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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,078	MONTE, WOODROW C.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 6-41* is/are pending in the application.

4a) Of the above claim(s) *10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3,6-9,11 and 13-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2, 3 and 6-41 are pending in the application as of the request for continued examination received on November 18, 2005. Of these, claims 10 and 12 have been withdrawn. Accordingly, claims 2, 3, 6-9, 11 and 13-41 are being examined on the merits herein.

Applicant's arguments received November 18, 2005, with respect to the rejection of claims 2, 3, 6-9 and 13-41 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claims have been fully considered and are persuasive. In particular, it is noted that the pending claims are drawn to the species of active that is an enzyme, as elected by Applicants in the response submitted March 12, 2002. It is noted that the specification exemplifies adding tablets having lactase, an enzyme active, to milk at a temperature at which lactase denatures (se page 21, in particular.) The specification further describes devices such as tablets, capsules and overlays that protect the enzyme active to inhibit the enzyme active from denaturing (see page 6, in particular.) The temperatures at which enzyme actives denature are also considered to be known in the art or can be readily determined as known to those of ordinary skill in the art. Accordingly, it is considered that the specification is enabling for a method of adding a device having active that is an enzyme to a food or cosmetic composition that is at or above a temperature at which the active denatures.

Accordingly, the rejection of claims 2, 3, 6-9 and 13-41 under 35 U.S.C. 112, first paragraph is withdrawn.

Applicant's arguments received November 18, 2005, with regards to the rejection of claims 2, 3, 6-9, and 13-41 under 35 U.S.C. 112, second paragraph, as being indefinite, have been fully considered but they are not persuasive. In particular, Applicant's amendment to recite "a temperature [that] at which the active denatures" in claims 2 and 31 does not remedy the indefiniteness of these claims and the claims depending therefrom. Accordingly, claims 2, 3, 6-9 and 13-41 remain rejected under 35 U.S.C. 112, second paragraph, and claim 11 is also being rejected herein under this paragraph.

Applicant's arguments received November 18, 2005 with respect to the rejection of claims 2, 3, 6-9, 11, 13-19, 22-26, 28 and 31-41 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,707,843 to Monte (hereinafter Monte '843) have been fully considered and are persuasive. In particular, Monte '843 does not specifically teach adding a device comprising an active to a composition while the composition is "at or above a temperature [that] at which the active denatures," as recited in the claims. Accordingly, the rejection of claims 2, 3, 6-9, 11, 13-19, 22-26, 28 and 31-41 under 35 U.S.C. 102(b) has been withdrawn.

Applicant's arguments received November 18, 2005 with respect to the rejection of claims 20-22, 23, 27, 29-30 and 40 under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,707,843 to Monte (hereinafter Monte '843), in view of U.S. Patent Nos. 5,578,336 and 5,424,299, both to Monte, have been fully considered and are persuasive. In particular, the Monte references do not specifically teach adding a device comprising an active to a composition while the composition is "at or above a temperature [that] at which the active denatures," as recited in the claims. Accordingly, the rejection of claims 20-22, 23, 27, 29-30 and 40 under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,707,843 to Monte (hereinafter Monte '843), in view of U.S. Patent Nos. 5,578,336 and 5,424,299, both to Monte, has been withdrawn.

Applicant's arguments received November 18, 2005 with respect to the rejection of claims 2, 3, 6-9, 11, 13-19, 22-26, 28 and 31-41under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 5,707,843 to Monte (hereinafter Monte '843) have been fully considered and are persuasive. In particular, the Monte '843 does not specifically claim adding a device comprising an active to a composition while the composition is "at or above a temperature [that] at which the active denatures," as recited in the claims. Accordingly, the rejection of claims 2, 3, 6-9, 11, 13-19, 22-26, 28 and 31-41under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 5,707,843 to Monte (hereinafter Monte '843), has been withdrawn.

The following new rejections have been necessitated by Applicant's amendments to the claims.

Claim Objections

Claim 2 is are objected to because of the grammatically incorrect phrase "at or above a temperature that at which the active denatures" (underline added.) The Examiner respectfully suggests deleting the unnecessary term "that" appearing in this claim.

Claim 25 is objected to because the term "composition" has been omitted following the phrase "lactose-containing" in the fourth line of the claim. Appropriate correction is required.

Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, claim 25, from which claim 31 depends, recites "including the lactose-converting active in the lactose-containing composition while the composition is at or above a temperature at which the active denatures," whereas claim 31 recites that the composition is at or above the temperature at which the active denatures or is destroyed. Thus, the scope of claim 31 is actually broader than that of claim 30, because it allows for a temperature at which the active is destroyed as well as the temperature at which the active is

denatured. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 6-9, 11 and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear what is meant by the recitation of "adding the device to the composition while the composition is at or above a temperature [that] at which the active denatures," as recited in claim 2, and "including the lactose-converting active in the lactose-containing [composition] while the composition is at or above a temperature at which the active denatures," as recited in claim 25. In particular, it is not clear whether the temperature of the composition is intended to be (i) at or above a temperature at which the active denatures in the absence of the device or other mechanism that protects the active, or (ii) at or above a temperature at which the active denatures in the presence of the device or other protecting mechanism. Is it intended that the temperature of the composition be at or above a temperature at which the active would otherwise denature if not provided in conjunction with the device or other protective mechanism, or is it intended that the temperature be such that the active provided with the device and/or other protective mechanism is at least partially denatured? The specification does not explicitly set forth

the denaturation temperature that is intended. Accordingly, as the metes and bounds of claims 2 and 25 are not clear, the claims are rejected as being indefinite under 35 U.S.C 112, second paragraph. Claims 3, 6-9, 11, 13-24 and 26-41 are rejected as being dependent upon indefinite claims.

In the interests of compact prosecution and for the purposes of applying prior art, claims 2 and 25 are being interpreted to mean that the composition is at or above a temperature at which the enzyme active denatures in the absence of the device or other protective mechanism.

Claim 26 is furthermore rejected under 35 U.S.C. 112, second paragraph, as having a lack of antecedent basis for the phrase "lactose converting substance." Claim 25, from which claim 26 depends, recites a "lactose-converting active" and a "lactose-containing composition," but does not recite a "lactose converting substance." Accordingly, it is not clear what "lactose converting substance" is being referred to, and thus claim 26 is indefinite under 35 U.S.C. 112, second paragraph. Appropriate correction is required.

Claims 27-29, 31, 33-35, 37-39 are rejected under 35 U.S.C. 112,second paragraph, as having a lack of antecedent basis for the term "the device" as recited in claims 27, 31, 33-35 and 37-39. Claim 25 from which these claims depend recites a "lactose-containing composition" and "a lactose-converting active," but does not recite a

"device." Accordingly, it is not clear what "device" is being referred to, and thus the claims are indefinite under 35 U.S.C. 112, second paragraph. Claims 28-29 are rejected as being dependent upon an indefinite claim. Appropriate correction is required.

In the interests of compact prosecution and for the purposes of applying prior art, the "device" as recited in these claims is being interpreted to mean the "lactose-converting active" as recited in claim 25.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,357,852 to Kohler et al, issued October 25, 1994.

Kohler et al. teaches a method of reducing lactose in milk or milk products (see abstract, in particular), and teaches that it is known to add a quantity of lactase enzyme to milk, and then pasteurize the milk and enzyme (see column 2, lines 8-30, in

particular), and thus bring the composition to a temperature at which the enzyme denatures. Accordingly, Kohler et al. teaches including the lactose-converting active in the composition while the composition is at or above the denaturing temperature, because the lactase enzyme has been added to the milk before pasteurization and is still present at the onset of pasteurization, and thus is "included" in the composition while the composition is at this temperature. Accordingly, claim 25 is anticipated by Kohler et al.

Regarding claim 26, Kohler et al. teaches providing lactase, an enzyme. Regarding claim 35, Kohler et al. teaches pasteurizing after the lactase enzyme has been added. Regarding claim 36, Kohler et al. teaches that the milk and enzyme are placed in a holding tank (see column 2, lines 9-25, in particular.) Regarding claim 37, Kohler et al. teaches adding lactase enzyme into raw milk in a batching tank (see column 2, lines 9-25, in particular.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6-9, 13-14, 23-25, 27-28, 31-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,902,617 to Patrea L. Pabst, issued May 11, 1999, in view of U.S. Patent No. 6,064,044 to Leno Jerome, issued May 16, 2000.

Pabst teaches an enzyme supplemented baby formula wherein the enzymes (the active) are provided in a form that is stable to storage in the formula but active when the formula reaches a portion of the gastrointestinal tract (see abstract, in particular.) Pabst teaches that the supplement can comprise an enzyme such as papain, which is typically inactivated (denatured) by cooking (see column 3, lines 45-65, in particular.) Pabst teaches that the papain is a protease that is approved for use in food and thus imparts a beneficial effect (see column 3, lines 45-65, in particular.) Pabst also teaches that the enzyme composition (enzyme active) can comprise lactase (see column 4, lines 1-10, in particular.) Pabst teaches that the enzymes can be stabilized by lyophilization as well as providing an enteric coating and/or microcapsule formulations (see column 2, lines

54-62 and column 6, lines 5-65, in particular.) Pabst teaches that the additive can be added to the baby formula at the time of feeding or in advance to allow pre-digestion of the substrate by the additives, and that modifications and variations in the methods of administration and preparation can be made by those of ordinary skill in the art (see column 6, line 60 through column 7, line 3, in particular.)

Accordingly, Pabst teaches providing a protective enteric coating and/or microcapsule formulation (a device) to protect a beneficial active such as an enzyme composition comprising papain that is inactivated (denatured) by cooking, and teaches that the formulation can be added in advance of feeding.

Pabst does not specifically teach that the baby formula enzyme supplement is added to the baby formula while the composition is at or above a temperature at which the active denatures, as recited in claim 2.

Jerome teaches an automated bottle temperature control system that provides the safe heating of baby formula prior to the feeding of infants (see abstract, in particular.) Thus, Jerome teaches that it is known to heat (cook) baby formula in advance of feeding.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to add the formula supplement of Pabst during cooking of

the formula, i.e. at a temperature at which papain denatures, because Pabst teaches that the supplement can be added to the formula prior to feeding to allow for pre-digestion of the formula substrate by the enzymes, and Jerome teaches that cooking of the formula is a standard step that is implement prior to feeding. Thus, one of ordinary skill in the art would have been motivated to provide the supplement during cooking of the formula, with the expectation of providing a suitable pre-digestion of the formula in advance of feeding while carrying out the formula cooking preparation step that is standard in the preparation of formula for feeding. Accordingly, claim 2 is obvious over the teachings of Pabst and Jerome.

Regarding the exact cooking temperature at which the baby formula is maintained, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize cooking temperature, according to the guidance provided by Pabst and Jerome, to provide a suitable baby formula preparation method. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 25, it is noted that Pabst teaches providing an enzyme active supplement that can comprise enzyme such as papain and lactase, and thus the supplement comprising lactase, papain and any other enzymes can be considered to be

a lactose-converting active. As discussed for claim 2 above, the teachings of Pabst and Jerome further render obvious the step of providing an active comprising lactase and papain to a lactose-containing composition, namely baby formula, while the composition is at or above a temperature at which the active denatures, because Pabst and Jerome teach that the papain part of the enzyme supplement active is inactivated (denatured) with cooking), and further teach that baby formula is typically cooked before feeding to infants. Accordingly, one of ordinary skill in the art would have been motivated to provide the enzyme supplement active during cooking of the formula, with the expectation of providing a suitable pre-digestion of the formula in advance of feeding while carrying out the formula cooking preparation step that is standard in the preparation of formula for feeding. Thus, claim 25 is obvious over the teachings of Pabst and Jerome.

Regarding the exact cooking temperature at which the baby formula is maintained, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize cooking temperature, according to the guidance provided by Pabst and Jerome, to provide a suitable baby formula preparation method. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 3, Pabst teaches providing papain, an enzyme. Regarding claim 6, Jerome teaches placing the formula in baby bottles (see column 1, lines 34-45, in particular), and thus teaches placing in a sealed container. Jerome also teaches a heating system with a container and a cover that is placed over the container having the bottles therein (see Figure 2 and column 3, lines 1-15), and thus teaches sealing the formula in a container.

Regarding claims 7-9, 21 and 36-38, the teachings of Pabst and Jerome render obvious adding the device to the composition while at or about the denaturing temperature, as discussed for claim 2 above. Jerome also teaches that the baby formula can be provided in a bottle, which can be placed in a heating housing (two types of containers.) Accordingly, one of ordinary skill in the art would find it obvious to provide the enzyme supplement to the baby formula while the baby formula is being kept in one of the containers as taught by Jerome. One of ordinary skill in the art would furthermore find it obvious to add the supplement before or after the composite is placed in the container, as recited in claims 8-9 and 37-38, because Pabst teaches that the supplement can be suitably added prior to feeding. Regarding claim 39, Jerome teaches that a cover can be provided on the temperature controlled system (see Figure 2, in particular), and thus teaches that the system can be sealed at some point during the temperature maintenance process.

Regarding claims 31-35, Jerome teaches that the bottle temperature control system is adapted to activate and deactivate a temperature control circuit according to the measured temperature of the water, to transfer energy into and out of the bottles. Accordingly Jerome teaches that the bottles are cooled if the temperature is at or greater than a preset level, as the temperature circuit is not activated in this case (see abstract, in particular.) Accordingly, one of ordinary skill in the art would find it obvious to provide the enzyme supplement to the baby formula while the baby formula is being kept in the temperature control system prior to feeding as taught by Jerome. One of ordinary skill in the art would furthermore find it obvious to add the supplement before or after cooling of the bottles, as recited in claims 33 and 34, because Pabst teaches that the supplement can be suitably added prior to feeding. Regarding claim 35, it would furthermore be obvious to further heat the bottles after the initial addition of the enzyme actives, because Jerome teaches that the control system is capable of temperature sensing and continuous heating and/or cooling of the bottles (see abstract, in particular.)

Regarding claims 13 and 28, Pabst teaches that the supplement can comprise an enteric coating (see column 6, lines 15-40, in particular), and thus teaches the exterior coating as recited in the claim. Regarding claims 14 and 27, Pabst and Jerome both teach baby formula, which is a food. Regarding claim 23, Pabst teaches that the enzyme formulation can be added as a concentrate similar to the way in which lactase is currently available for treatment of milk (see column 6, lines 50-65, in particular), and

further teaches that tablets are a form in which lactase is currently available (see column 4, lines 1-10, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the enzyme supplement in tablet form, as Pabst teaches that this is a suitable means of administration.. Regarding claim 24, Pabst teaches providing an enteric coating as well as microcapsules, as discussed above, which are considered to be overlays because they provide a cover overlying the interior active enzymes.

Regarding claim 41, Pabst teaches that an example of a microcapsule includes a microcapsule that releases as a function of pH, such as at a pH of 6.5 to 7.0, which is within 0.5 of the claimed range of 6.0 or less. Pabst also teaches that many of the enzymes that can be included in the supplement active include those that have an optimum stability at a pH of about 6, such as bile salt lipase (see column 5, lines 1-15, in particular) and alpha-amylase (see column 4, lines 55-60, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the pH of the enzyme supplement, according to the guidance provided by Pabst, to provide a supplement having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,707,843 to Woodrow C. Monte, issued January 13, 1998, in view of U.S. Patent No. 5,902,617 to Patrea Pabst, issued May 11, 1999.

Monte teaches providing a sterilized enzyme composition (device having an enzyme active) for addition to a pasteurized dairy product to reduce the lactose content of the dairy product (see abstract, in particular.) Monte teaches that the method comprises heating the dairy product to sterilize and pasteurize the product (a temperature at which the active lactase denatures), and adding the enzyme to the pasteurized product (see column 4, lines 30-46, in particular.) Monte furthermore teaches the desirability of providing the lactase enzyme to the dairy product for a sufficient amount of time before ingestion of the dairy product, to allow for sufficient hydrolyzation of the lactose (see column 4, line 56 through column 5, line 24, in particular.) Monte also teaches the desirability of providing a composition that hydrolyzes lactose even while the product is being ingested (see column 2,lines 18-45, in particular.) Thus, Monte teaches providing a device comprising the enzyme lactase to a composition comprising lactose to impart a beneficial effect to the composition.

Monte does not specifically teach adding the lactase enzyme to the dairy product while the product is being pasteurized or is at a temperature that denatures the lactase enzyme, as recited in claim 2.

Pabst teaches that enzymes can be added to baby formula, a dairy product, to imitate the effect of those present in normal breast milk (see abstract, in particular.) Pabst teaches that the enzymes are provided in a form that is stable in storage but active when it reaches a portion of the gastrointestinal tract (see abstract, in particular.) Pabst teaches that the formulations are stabilized and can be provided with an enteric coating (a device) hat preserves maximal enzymatic activity until the enzyme is released in the small intestine (see column 2, lines 54-65, in particular.) Pabst teaches that enzymes included in the formulation can include lactase (see column 4, lines 1-10, in particular), and points out that the particular enzyme papain that the enteric coating protects against inactivation by cooking (see column 3, lines 55-68, in particular), and also teaches the protection of a lipase that is not stable to pasteurization (see column 5, lines 1-15, in particular.) Accordingly, Pabst teaches that stable formulations of enzymes, such as enzyme formulations having enteric coatings, can be provided to improve the thermal stability of enzymes, and also to allow continued activity of the enzymes even after ingestion.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the dairy pasteurization and lactase enzyme addition method of Monte by adding the stabilized lactase-containing enzyme composition of Pabst at a high temperature, such as the pasteurization temperature used to pasteurize the dairy product, because Monte teaches the desirability of adding the enzyme in sufficient time to provide sufficient hydrolysis of the lactose, and Pabst

teaches that the stabilized enzyme compositions have improved thermal stability and allow for continued activity of the enzymes even after ingestion. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to add the enzyme composition of Pabst during or shortly after the pasteurization of the dairy product, and thus at a temperature at or above the temperature at which the lactase denatures, with the expectation of providing the composition early on in the dairy product preparation process to allow time for hydrolyzation of a sufficient amount of lactose before ingesting and/or packaging. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the temperature of the dairy product at the point in which the enzyme composition is added, according to the guidance provided by Pabst and Monte, to provide a desired level of lactose hydrolysis. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claim 2 is obvious over the teachings of Monte and Pabst.

Regarding claim 25, the teachings of Monte and Pabst render obvious providing an enzyme composition having a lactose-converting active (lactase) to a lactose-containing composition (dairy product) at a temperature that is at or near pasteurization temperatures, and that is thus at or above temperatures at which the active denatures. Accordingly, claim 25 is obvious over the teachings of Monte and Pabst.

Regarding claims 3, 11, 15 and 26, Monte and Pabst both teach providing lactase, a lactose hydrolyzing enzyme that converts lactose to glucose. Regarding claim 6, Monte teaches that the dairy product and enzyme can be packaged (see column 6, lines 20-55, in particular), and thus teaches providing the composition in a container and sealing.

Regarding claim 7 and 36, Monte teaches that the composition can be stored and packaged after pasteurization (see column 6, lines 20-55, in particular.) Accordingly, it is considered that it would be obvious to add the composition to a container at a temperature that is at or near the pasteurization temperature, such as a temperature that is at or above the denaturing temperature as recited in the claim. Regarding claims 8-9 and 37-38, it is considered that one of ordinary skill in the art would find it obvious to vary and or optimize the steps of adding the enzyme composition to the dairy product, such as adding before or after the dairy product had been added to a container, according to the guidance provided by Monte and Pabst to provide a desired sequence of dairy product preparation steps. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 39, Monte teaches that the dairy product can be packaged and stored, and thus teaches sealing the composition.

Regarding claim 13, Pabst teaches that the enzyme composition can comprise an enteric coating, as discussed for claim 12 above, and thus teaches the claimed exterior coating. Regarding claim 14, Monte teaches the treatment of a dairy product, which is a food.

Regarding claims 16-19 it is noted that the combined teachings of Monte and Pabst renders the addition of the claimed enzyme composition obvious. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of lactase provided and/or the duration of lactose hydrolyzation, according to the guidance provided by Monte and Pabst, to provide a desired percent conversion of the lactose, such as the percent conversions as claimed. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 21, it is noted that since the combined teachings of Monte and Pabst renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the

properties, namely the denaturing temperature of 180 degrees, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 23, Pabst teaches that the enzyme formulation can be added as a concentrate similar to the way in which lactase is currently available for treatment of milk (see column 6, lines 50-65, in particular), and further teaches that tablets are a form in which lactase is currently available (see column 4, lines 1-10, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the enzyme supplement in tablet form, as Pabst teaches that this is a suitable means of administration. Regarding claims 24 and 27-28, Pabst teaches the enzyme supplement composition can comprise an enteric coating, and thus is considered to teach an overlay because the enteric coating is overlying the interior enzyme composition, and is also an external coating.

Regarding claims 30-31, Monte teaches heating the dairy product to pasteurization, which is typically at or about 180°F, and is at or above a temperature at which the lactase denatures. Furthermore, it is considered that one of ordinary skill in

the art at the time the invention was made would have found it obvious to vary and/or optimize the temperature of the dairy product pasteurization, according to the guidance provided by Monte et al, to provide a suitably pasteurized dairy product. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 32-34, Monte teaches that the composition can be frozen for storage, and teaches that the composition can be made into a milk shake (see column 2, lines 1-15, in particular), and thus teaches cooling the composition as recited in claim 32. It furthermore would have been obvious to add the lactose-containing enzyme before or after cooling, as recited in claims 33-34, because Monte teaches the composition can be cooled for storage, and that a milk shake can be formed from the composition, and thus one of ordinary skill in the art would find it obvious to combine in various ways the steps of cooling for storage, thawing, adding enzyme and making milkshakes, as taught by Monte.

Regarding claim 35, the teachings of Monte and Pabst render obvious providing an enzyme composition having a lactose-converting active (lactase) to a lactose-containing composition (dairy product) at a temperature that is at or near pasteurization temperatures, and that is thus at or above temperatures at which the active denatures, because Monte and Pabst teach the desirability of providing the enzyme early in the

production process to allow sufficient time for the lactose to hydrolyze. Accordingly, the method of claim 35 of heating to the denaturing temperature after the enzyme is added is obvious over the teachings of Monte and Pabst.

Regarding claim 41, Monte teaches that is it important to maintain the pH of the enzyme composition between 1.5 to 6.0 to reduce microbial growth (see column 3, lines 5-35, in particular.)

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monte and Pabst as applied to claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41, above, in view of U.S. Patent No. 4,035,981 to Braun et al, issued July 19, 1977.

Monte and Pabst are applied as discussed for claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41 above, and render obvious the claimed method of including a lactose-converting active to a lactose-containing composition while the composition is at a temperature at or above which the active denatures, and also teach providing the active in tablet form. Monte further emphasizes the importance of providing a sterilized enzyme composition so the milk product will not be microbially contaminated (see column 6, lines 1-5, in particular.)

Monte and Pabst do not specifically teach sterilizing the tablet with gamma rays, as recited in the claim.

However, Braun et al. teaches that gamma radiation can be used to kill bacteria for materials used in milk production and processing, such as milk containers and lid materials (see column 2, lines 15-35, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to sterilize the enzyme tablets of Monte and Pabst with the gamma rays of Braun et al, with the expectation of providing a means for sterilizing the tablet to render it suitable for use with milk products.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monte and Pabst as applied to claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41, above or over Pabst and Jerome as applied to claims 2, 3, 6-9, 13-14, 23-25, 27-28, 31-39 and 41 above, in view of U.S. Patent No. 5,578,336 to Monte (hereinafter Monte '336, issued November 26, 1996.)

Pabst and Jerome and Monte and Jerome are applied as discussed above, and teach providing a stabilized enzyme containing composition, such as a coated composition, to a dairy product.

The references do not specifically teach that the enzyme composition comprises a coating that is a sugar coating, as recited in claim 20.

Monte '336 teaches that a sugar coating can be provided about a composition comprising an enzyme and protects the composition from biodegradation and decomposition and from spoilage due to contact with oxygen and water (see columns 1-3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sugar coating of Monte '336 in the composition of Pabst and Jerome or Monte and Pabst, with the expectation of providing a coating that protects and stabilizes enzyme-containing compositions.

Claims 22 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte and Pabst as applied to claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41 above, in view of U.S. Patent No. 5,424,299 to Monte (hereinafter Monte '299), issued June 13, 1995.

Monte and Pabst are applied as discussed for claims 2-3, 6-9, 11, 13-19, 21, 23-28, 30-39 and 41 above, and teach providing lactose to a dairy product at a temperature that is at or above the denaturing temperature. Monte and Pabst do not specifically teach that the dairy product is an enteral food, as recited in claims 22 and 40.

Monte '299 teaches that a composition comprising beta galactosidase (lactase) can be provided as an enteral composition to clear unwanted starches and other materials form feeding tubes (see abstract and column 4, lines 13-45, in particular.)

Accordingly, it would be obvious to one of ordinary skill in the art at the time the invention was made to provide the lactase-containing composition of Monte and Pabst as an enteral food as taught by Monte '299, because Monte teaches that a lactase-containing composition provides benefits as an enteral composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 6-9, 11, 13-19, 22-28 and 30-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8 of U.S. Patent No. 5.707,843 to Monte, issued January 13, 1998, in view of the teachings of U.S. Patent No. 5,902,617 to Pabst, issued May 11, 1999.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the Monte patent claims pasteurizing a milk product and adding a lactase enzyme composition, whereas Pabst teaches stabilized enzyme formulations that have thermal stability provide improved delivery of the active enzymes, as set forth in the 103 rejection discussed above. Accordingly, the instant claims are not patentably distinct over the Monte patent in view of the teachings Pabst.

Response to Arguments

Applicant's arguments with respect to claims 2-3, 6-9, 11 and 13-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

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